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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,551	06/29/2006	Xin Qi	36290-0408-00-US	4948

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EXAMINER	
HOLLOMAN, NANNETTE	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,551	QI ET AL.	
	Examiner	Art Unit	
	NANNETTE HOLLOMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,10-17,31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) *34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,10-17,31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on September 16, 2009. Applicants' arguments, filed September 16, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Newly submitted claim 36 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 2-4, 10-17, 31 and 33, drawn to a method of treating hypoglycaemia in an individual.

Group II, claim(s) 34, drawn to a method of treating glycogen storage disease in an individual.

Group III, claim(s) 35, drawn to a method of treating liver disease in an individual.

Group IV, claim(s) 36, drawn to a method of treating Type I diabetes or Type II diabetes in an individual in need of such treatment.

The technical feature linking the claims is administering a food composition. Prior art exists which causes the method in the current application to lack a special technical feature. Kaufman (US Patent 5,605,893) disclose a food product for treating, which meets the limitation of administration (Abstract)

As a result, no special technical feature exists among the different groups because the inventions in Groups I-IV fail to make a contribution over the prior art and are therefore not "special."

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 36 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 10-17, 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "semi-crystalline" in claims 2-3, 31 and 33 is a relative term which renders the claims indefinite. The term "semi-crystalline" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no direction to the amount of crystallinity that would be encompassed by "semi-crystalline".

Claim Rejections - 35 USC § 103 (New Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 2-4, 10-11, 13-16, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman (US Patent No. 5,605,893, previously disclosed) by itself or in view of Anderson et al. (Starch, Vol. 54, 2002, pp 401-409).

Kaufman discloses a therapeutic food composition containing starch, such as slowly absorbed or digested complex carbohydrate, preferably cornstarch, for treatment of diabetic patients to prevent hypoglycemic episodes and diminish fluctuations in blood sugar levels (instant claims 2-3 and 33) (Abstract). Kaufman further discloses treating patients having glycogen storage disease and Type I or II diabetes (instant claims 10-11) (column 1, lines 64-65 and column 2, lines 46). Kaufman discloses maintaining blood sugar levels above 60 mg/dl (converted to 3.33mmol/l) for as long as 8-9 hours, which meets the limitation of instant claims 15 and 16 (column 4, lines 28-30).

Kaufman differs from the instant claims insofar as it does not disclose a heat moisture-treated or annealing-treated, semi-crystalline starch. It is known that the consumption of starch by a human increases glucose levels[1], which would in fact treat hypoglycaemia. With the absence of the criticality of any specific starch or unexpected results one of ordinary skill in the art would expect any starch to increase the level of glucose therefore treat hypoglycaemia.

[1] Metabolic Energy (Stryer, Biochemistry, Metabolic Energy, Third Edition, p. 342, 1988, previously disclosed). This reference is used to disclose that starch is hydrolyzed into glucose when ingested by humans and is not relied upon for the basis of the rejection.

Anderson et al. disclose heat moisture treated waxy[2] corn starch (p. 406, Fig. 6 and column 1, lines 5-9); wherein the starches crystallize from said treatment (p. 408, conclusion), which is being understood to meet the limitation of semi-crystalline. The instant specification defines a "waxy" starch as containing <20% amylase (80% amylopectin) (Specification, p. 19, lines 17-18).

Anderson et al. differs from the instant claims insofar as it does not disclose a method of treating hypoglycaemia in an individual in need of such treatment.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. MPEP 2144.07. Therefore, it would have been obvious to one of ordinary skill in the art to have used a heat moisture-treated, semi-crystalline starch as the complex carbohydrate in the food composition of Kaufman since heat moisture-treated, semi-crystalline starch is known in the art as disclosed by Anderson et al.

The instructions of instant claim 31 are non-functional descriptive material. Patentable weight need not be given to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See MPEP 2106.01.

[2] Schmiedel et al. (US Patent Pub. No. 2003/0054501). This reference is disclosed to show that waxy starches are defined as a starch with amylose content of <10% (paragraph [0033]) and is not used as the basis for the rejection.

2) Claims 2-4, 11-14, 17, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson et al. (WO 02/34271 A1, previously disclosed) by itself or in view of Anderson et al. (Starch, Vol. 54, 2002, pp 401-409).

Hansson et al., which is directed to a composition of heat treated starch for the prevention of hypoglycaemia in patients with diabetes or liver disease (instant claim 2-3, 11-12 and 33) (Abstract and p. 8, lines 9-11, claim 6), discloses a method for stabilizing the blood sugar levels and avoiding the oscillation between unhealthy high and low blood sugar levels (p. 8, lines 27-28). Hansson et al. disclose administering a patient about 0.1 to 1.0g starch per kg body weight, which if given to an average size adult (87 kg) would meet the limitation of instant claim 17 (p. 2, lines 20-21)

Hansson et al. differ from the instant claims insofar as it does not disclose a heat moisture-treated or annealing-treated, semi-crystalline starch.

Anderson et al. disclose heat moisture treated waxy[3] corn starch (p. 406, Fig. 6 and column 1, lines 5-9); wherein the starches crystallize from said treatment (p. 408, conclusion), which is being understood to meet the limitation of semi-crystalline. The instant specification defines a "waxy" starch as containing <20% amylase (80% amylopectin) (Specification, p. 19, lines 17-18).

Anderson et al. differs from the instant claims insofar as it does not disclose a method of treating hypoglycaemia in an individual in need of such treatment. It is known

[3] Schmiedel et al. (US Patent Pub. No. 2003/0054501). This reference is disclosed to show that waxy starches are defined as a starch with amylose content of <10% (paragraph [0033]) and is not used as the basis for the rejection.

that the consumption of starch by a human increases glucose levels[4], which would in fact treat hypoglycaemia. With the absence of the criticality of any specific starch or unexpected results one of ordinary skill in the art would expect any starch to increase the level of glucose therefore treat hypoglycaemia.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. MPEP 2144.07. Therefore, it would have been obvious to one of ordinary skill in the art to have used a heat moisture-treated, semi-crystalline starch as the complex carbohydrate in the food composition of Hansson since heat moisture-treated, semi-crystalline starch is known in the art as disclosed by Anderson et al.

The instructions of instant claim 31 are non-functional descriptive material. Patentable weight need not be given to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See MPEP 2106.01.

No claim is allowed.

[4] Metabolic Energy (Stryer, Biochemistry, Metabolic Energy, Third Edition, p. 342, 1988, previously disclosed). This reference is used to disclose that starch is hydrolyzed into glucose when ingested by humans and is not relied upon for the basis of the rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./
Examiner, Art Unit 1612
/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612